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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,148	11/05/2003	Michael H. Jones	14875-042004	7576
26161	7590	04/17/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			KIM, YUNSOO	
		ART UNIT	PAPER NUMBER	
		1644		

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/702,148	JONES, MICHAEL H.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 February 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 25 and 29-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 29 and 40-44 is/are allowed.
- 6) Claim(s) 25, 30-39 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/2/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicants' remarks mailed 2/2/06 have been acknowledged.  
Claims 29-44 have been added.  
Claim 25 and the specification have been amended.  
Claims 25 and 29-44 are pending.
2. Applicants' IDS filed on 2/2/06 has been considered.
3. Applicants are required to provide a mark up version of amendment to specification.
4. In view of applicants' amendment to the claims, the rejection under 35 U.S.C.101 and 112 1st and the 2<sup>nd</sup> paragraphs (see sections 9 -15) set forth in the office action mailed 8/3/05 has been withdrawn.
5. The following new grounds of rejections are necessitated by Applicant's amendment to claim filed on 2/2/06.  
  
6. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 30, 31, 33, 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.  
The term "gene" and the phrase "highly stringent conditions" recited in claims 30, 31 and dependent claims thereof do not clearly define metes and bounds of the invention.
8. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1644

9. Claims 25, 32 and 35-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for an antibody binding to the amino acid sequence consisting of SEQ ID NOs:1, 13, 21, 27 or 29, does not reasonably provide enablement for any antibody binding to at least 95% amino acid sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

There is insufficient guidance in the specification as filed as to how the skilled artisan would make and use the antibody to polypeptide having at least 95% amino acid sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29 recited in the instant claim. A person of skill in the art would not know which amino acid is essential to retain binding to SEQ ID NOs:1, 13, 21, 27 or 29. There is insufficient guidance to direct a person of skill in the art to select particular antigen binding fragment. Without detailed direction as to which amino acid is essential to maintain binding to SEQ ID NOs:1, 13, 21, 27 or 29, a person of skill in the art would not be able to determine which peptides are capable of binding to an antibody or antigen binding fragment without undue experimentation.

Minor structural differences among structurally related compounds can result in substantially different in solubility, adsorption, or biological activities. Therefore, structurally unrelated compounds comprising antibodies or antigen-binding fragment would be expected to have greater differences in their activities. Colman et al. (Research in Immunology, 145(1):33-36, 1994, provided in office action mailed 8/3/05) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding.

Furthermore, Applicant has no working examples demonstrating binding at least 95% sequence identity to the amino acids SEQ ID NOs:1, 13, 21, 27 or 29.

Accordingly, the specification is not enabling for any antibody binding to the polypeptide having at least 95% sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29 because the specification does not adequately disclose how to make polypeptide having at least 95% sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29 that are functional for practice of the claimed invention.

Art Unit: 1644

10. Claims 25, 32 and 35-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an antibody capable of binding to the amino acid sequence consisting of SEQ ID NOs:1, 13, 21, 27 or 29; however, applicant is not in possession of any antibody capable of binding to any polypeptide having at least 95% sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29. The phrase "having at least 95% sequence identity to SEQ ID NO:1 (for example)" includes  $1.8 \times 10^{40}$  different amino acid combinations. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

11. Claims 29 and 40-44 are allowable.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1644

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim

Patent Examiner

Technology Center 1600

April 6, 2006



Patrick J. Nolan, Ph.D.

Primary Examiner

Technology Center 1600